

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Start-up Option License: Use of Oligodeoxynucleotide as Neuroprotectants in Cerebral and Other Ischemic Injury

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive start-up option license to practice the inventions embodied in: (E-147-1999/0 &1) US provisional patent application No. 60/128/898 filed 4/12/1999, and PCT application No. PCT/US00/09839 filed 4/12/2000, and U.S. patent No. 6,977,245 filed 02/06/2002 issued 12/20/2005, and U.S. patent No. 7,960,356 filed 05/17/2005 and issued 06/14/2011, and EP1176966 granted 4/3/2013, each entitled "Oligodeoxynucleotide and Its Use to Induce an Immune Response"; and (E-036-2005/0) US provisional patent application No. 60/713,547 filed August 31, 2005, and PCT application No. PCT/US2006/033774 filed August 28, 2006, and US patent 7,892,569 filed 8/31/2005 issued 2/22/2011, and Canada application number 2620582 filed 2/28/08, and Australia patent 2006284889 filed 8/28/2006 issued 12/1/11, and Japan patent 5481068 filed 8/28/2006 issued 2/21/2014, each entitled "Method of Altering an Immune Response Induced by CpG Oligodeoxynucleotides"; and (E-214-2001/0) US provisional patent application No. 60/312,190 filed August 14, 2001, and PCT application No. PCT/US202/025732, and US patent 7,354,909 filed February 2, 2004 issued April 8, 2008, and

US patent 7,959,934 filed March 28, 2008 issued June 14, 2011, each entitled "Method for Rapid Generation of Mature Dendritic Cells" by Klinman et al. (FDA), to Neuralexo, LLC, having a place of business at 17367 Canal Circle Lake Oswego, Oregon 97035.

The United States of America is an assignee to the patent rights of these inventions.

The prospective exclusive start-up option licensed territory may be worldwide, and the field of use may be limited to: preventative treatment for ischemic injury in organs.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: fennea@mail.nih.gov; Telephone: 424-297-0336; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

This invention relates to compositions and methods of use of oligodeoxynucleotides (ODNs) expressing CpG motifs to induce immune responses. These ODN motifs trigger immune system responses which may mediate inflammatory responses to tissue injury, such as those responses following ischemic damage to the central nervous system. Structural differences between various ODNs may stimulate distinct cell populations, allowing selective targeting of immune responses for therapeutic purposes. Non-human primate and animal models using specific ODNs for pharmacological preconditioning have shown that ODNs may act

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therapeutically as neuroprotectants from ischemic damage. These TLR ligands as may be useful

therapeutically as neuroprotectants in ischemic injury.

The prospective exclusive start-up option license will be royalty bearing and will comply

with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive start-

up option license may be granted unless the NIH receives written evidence and argument that

establishes that the grant of the license would not be consistent with the requirements of 35

U.S.C. 209 and 37 CFR 404 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will

be treated as objections to the grant of the contemplated exclusive start-up option license.

Comments and objections submitted in response to this notice will not be made available for

public inspection, and, to the extent permitted by law, will not be released under the Freedom of

Information Act, 5 U.S.C. 552.

Dated: August 25, 2014.

Richard U. Rodriguez,

Division of Technology Development and Transfer,

Office of Technology Transfer,

National Institutes of Health.

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